

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS)
LP,)
and)
ASTRAZENECA UK LIMITED,) Civil Action No. 07-807 JJF
)
and)
IPR PHARMACEUTICALS, INC.,)
and)
SHIONOGI SEIYAKU KABUSHIKI)
KAISHA,)
Plaintiffs,)
v.)
SANDOZ INC.,)
Defendant.)

**ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS
OF DEFENDANT SANDOZ, INC.**

Defendant Sandoz, Inc. ("Sandoz") answers the Complaint of Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "AstraZeneca" or "Plaintiffs") as follows, wherein numbered paragraphs 1-27 below correspond to the numbered paragraphs in the Complaint:

1. Sandoz admits that it has filed an Abbreviated New Drug Application (“ANDA”) relating to Crestor® and that this is an action for patent infringement, and denies the remaining allegations in Paragraph 1 of the Complaint.

Parties

2. Sandoz is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 of the Complaint, and therefore denies same.

3. Sandoz is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 of the Complaint, and therefore denies same.

4. Sandoz is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of the Complaint, and therefore denies same.

5. Sandoz is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5 of the Complaint, and therefore denies same.

6. Admitted (However, there is an error in Sandoz’s letter notifying Plaintiffs of the Sandoz ANDA and the certifications made to the FDA in that Sandoz Inc. is a Colorado corporation, not a Delaware corporation.)

Background

7. Sandoz is without knowledge or information sufficient to form a belief as to the truth of the allegation that “AstraZeneca is IPR’s authorized agent for matters related to NDA No. 021366,” and therefore denies same. Sandoz admits the remaining allegations in Paragraph 7 of the Complaint.

8. Sandoz admits that Crestor® (rosuvastatin calcium) is a prescription drug, is a statin, and is used to treat high cholesterol. Sandoz is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 8 of the Complaint, and therefore denies same.

9. Sandoz admits that at least one Plaintiff markets Crestor® Tablets in the United States. Sandoz is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 9 of the Complaint, and therefore denies same.

10. Admitted.

11. Admitted.

12. Admitted.

Jurisdiction And Venue

13. Sandoz admits that the Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), but denies that this Court has jurisdiction over any claims asserted by Plaintiffs under 28 U.S.C. §§ 2201 or 2202.

14. Sandoz denies that it is incorporated in Delaware, and denies that it maintains systematic and continuous contacts with the State of Delaware sufficient to allow jurisdiction to be exercised over it. However, for purposes of this action only, Sandoz consents to the jurisdiction of this Court.

15. Admitted.

Count I

Infringement Of United States Patent No. RE37,314 Under 35 U.S.C. § 271(e)(2)

16. Sandoz incorporates by reference paragraphs 1-15 of this Answer as if fully set forth herein.

17. Sandoz admits that U.S. Patent No. RE37,314 ("the 314 patent") was reissued by the United States Patent and Trademark Office on August 7, 2001, and that a copy of the '314 patent was attached to the Complaint, is without knowledge or information sufficient to form a belief as to whether Plaintiffs hold all substantial rights in the '314 patent and have the right to sue for infringement thereof, and denies the remaining allegations in Paragraph 17 of the Complaint.

18. Admitted, except that Sandoz alleged in its certification that the '314 patent is "invalid and/or unenforceable".

19. Sandoz denies that Sandoz Rosuvastatin Calcium Tablets are covered by any valid and enforceable claim of the '314 patent, and therefore denies the allegations in Paragraph 19 of the Complaint.

20. Sandoz admits that the submission to FDA of Sandoz's ANDA No. 79-171 to obtain approval for the commercial manufacture, use or sale of the Sandoz Rosuvastatin Calcium Tablets before the expiration of the '314 patent is recognized as an artificial act of infringement for purposes of conferring subject matter jurisdiction in the courts, and Sandoz otherwise denies the allegations of Paragraph 20 of the Complaint.

21. Denied.

Count II

Infringement Of United States Patent No. RE37,314 Under 35 U.S.C. § 271(a)

22. Sandoz incorporates by reference paragraphs 1-21 of this Answer as if fully set forth herein.

23. Denied.

24. Denied.

25. Denied.

26. Denied.

27. Denied, and assumes that "Sandoz", and not Cobalt", was intended.

ASTRAZENECA'S PRAYER FOR RELIEF

28. Sandoz denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief.

SANDOZ'S AFFIRMATIVE DEFENSES

First Affirmative Defense – Invalidity Of The '314 Patent

29. One or more claims of the '314 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101 *et seq.*

Second Affirmative Defense - Unenforceability Of The '314 Patent

30. On information and belief, the '314 patent is unenforceable due to the inequitable conduct of one or more persons who owed a duty of candor to the United States Patent and Trademark Office ("PTO") with respect to the '314 patent and/or U.S. Patent No. 5,260,440 ("the '440 patent") who, with the intent to deceive the PTO, violated their duty of candor to the PTO by intentionally failing to disclose material information to the PTO and by submitting a declaration in support of patentability that contained false and misleading information.

31. The U.S. patent application which issued as the '440 patent was filed with the PTO by Wenderoth, Lind & Ponack on June 12, 1992, and claims priority to Japanese Application Serial No. 188015, filed July 1, 1991.

32. The U.S. patent application for the '440 patent lists Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe as inventors.

33. The '440 patent was issued by the PTO on November 9, 1993.

34. European patent application serial number 92111090.4 ("Corresponding European Patent Application") is the European counterpart to the U.S. application for the '440 patent.

35. The Corresponding European Patent Application was filed with the European Patent Office by Vossius & Partner on June 30, 1992, and claims priority to Japanese Application Serial No. 188015.

36. The Corresponding European Patent Application lists as inventors Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe.

37. As filed, claim 1 of the Corresponding European Patent Application was identical to original claim 1 of the U.S. Patent application for the '440 patent.

38. On October 7, 1992, the European Patent Office transmitted a European search report ("European Search Report") concerning application number 92111090.4 to Vossius & Partner, the patent attorneys and/or agents responsible for prosecuting the Corresponding European Patent Application in the European Patent Office.

39. Under "DOCUMENTS CONSIDERED TO BE RELEVANT", the European Search Report listed one document, "EP-A-0 367 895 (SANDOZ)".

40. The European Search Report stated that EP-A-0 367 895 (SANDOZ) was a category "X" reference which, according to the European Search Report, is "particularly relevant if taken alone."

41. On information and belief, the named inventors and/or one or more other persons owing a duty of candor to the PTO were aware that the reference EP-A-0 367 895 (SANDOZ) was cited in the European Search Report as a Category "X" reference.

42. On August 27, 1998, Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe filed an application to reissue the '440 patent ("Reissue Application").

43. In a declaration filed in support of the Reissue Application ("Declaration"), it is stated that: "Patentee claimed more than he had a right to claim by reason of the disclosure of European Patent Application 0 367 895, published May 16, 1990. The amended claims of the reissue application are considered to fully overcome any grounds for unpatentability based upon this reference."

44. In the Reissue Application, Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe acknowledged that EP-A-0 367 895 (SANDOZ) was material to the application that issued as the '440 patent.

45. EP-A-0 367 895 (SANDOZ) was material to the application that issued as the '440 patent.

46. The Reissue Application issued as the '314 patent on August 7, 2001.

47. The named inventors and/or one or more other persons owing a duty of candor to the PTO failed to advise the PTO Patent Examiner responsible for prosecuting the '440 patent that EP-A-0 367 895 (SANDOZ) was cited in the European Search Report issued in the Corresponding European Patent Application, and such failure to advise constituted a material misstatement and/or misrepresentation and/or omission.

48. Upon information and belief, the failure to advise the PTO of EP-A-0 367 895 (SANDOZ) was carried out with the intent to deceive the PTO Patent Examiner so as to induce the PTO to issue the '440 patent.

49. In the Declaration in the Reissue Application, it was stated that: "All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant." The named inventors and/or one or more other persons owing a duty of candor to

the PTO submitted the Declaration in support of patentability, and such submission constituted a material misstatement and/or misrepresentation and/or omission and, upon information and belief, was made with intent to deceive the Patent Examiner so as to induce the PTO to issue the '314 patent.

Third Affirmative Defense – Sandoz's Rosuvastatin Calcium Tablets Do Not Infringe Any Valid Claim Of The '314 Patent

50. Sandoz's Rosuvastatin Calcium Tablets do not infringe any valid and enforceable claim of the '314 patent.

Fourth Affirmative Defense – Failure To State A Claim For Relief Under 35 U.S.C. § 271(a)

51. In Count II of the Complaint, Plaintiffs have failed to state a claim upon which relief can be granted.

Fifth Affirmative Defense – Lack Of Subject Matter Jurisdiction

52. The Court lacks subject matter jurisdiction over Count II of the Complaint.

SANDOZ'S COUNTERCLAIMS

Without waiver of any defense, Sandoz counterclaims as follows against Plaintiffs for a declaratory judgment that the '314 patent is invalid and unenforceable, and that U.S. Patent No. 6,316,460 ("the '460 patent"), U.S. Patent No. 6,858,618 ("the '618 patent") and U.S. Patent No. 6,589,959 ("the '959 patent") are invalid and not infringed, as follows:

Allegations Pertaining To All Of Sandoz's Counterclaims

53. The counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

54. Subject matter jurisdiction of these counterclaims is proper under 28 U.S.C. §§ 1331 and 1338(a) and Rule 13, Fed. R. Civ. P.

55. Venue as to Sandoz's counterclaims is proper under 28 U.S.C. §§ 1391(c) and 1400(b), and because Plaintiffs have commenced the underlying action in this District.

56. Counterclaim plaintiff Sandoz is a corporation operating and existing under the laws of the State of Colorado with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

57. On information and belief, counterclaim defendant AstraZeneca Pharmaceuticals LP is a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. Personal jurisdiction over AstraZeneca Pharmaceuticals LP is proper because AstraZeneca Pharmaceuticals LP is incorporated in Delaware and has purposely availed itself of the privilege of doing business in that State and has purposefully availed itself of this forum's benefits and privileges in this action. Further, AstraZeneca Pharmaceuticals LP maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

58. On information and belief, counterclaim defendant AstraZeneca UK Limited is a corporation operating and existing under the laws of the United Kingdom with its principal place of business at 15 Stanhope Gate, London W1K 1LN, England. Personal jurisdiction over AstraZeneca UK Limited is proper because AstraZeneca UK Limited has purposely availed itself of the privilege of doing business in Delaware and has purposefully availed itself of this forum's benefits and privileges in this action. Further, AstraZeneca UK Limited maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

59. On information and belief, counterclaim defendant IPR Pharmaceuticals, Inc. is a corporation operating and existing under the laws of Puerto Rico with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729. Personal jurisdiction over IPR Pharmaceuticals, Inc. is proper because IPR Pharmaceuticals, Inc. has purposely availed itself of the privilege of doing business in Delaware and has purposefully availed itself of this forum's benefits and privileges in this action. Further, IPR Pharmaceuticals, Inc. maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

60. On information and belief, counterclaim defendant Shionogi Seiyaku Kabushiki Kaisha is a corporation operating and existing under the laws of Japan with its principal place of business at 1-9, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045 Japan. Personal jurisdiction over Shionogi Seiyaku Kabushiki Kaisha is proper because Shionogi Seiyaku Kabushiki Kaisha has purposely availed itself of the privilege of doing business in Delaware and has purposefully availed itself of this forum's benefits and privileges in this action. Further, Shionogi Seiyaku Kabushiki Kaisha maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

61. The publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), identifies drug products approved for sale by the Food and Drug Administration (the "FDA") under the Federal Food, Drug, and Cosmetic Act, and the Orange Book lists patents that protect approved drug products and their uses.

62. The Orange Book lists the '314 patent, the '460 patent and the '618 patent with respect to rosuvastatin calcium tablets. On information and belief, the '959 patent was also listed in the Orange Book with respect to rosuvastatin calcium tablets, but was delisted sometime in 2007.

63. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 U.S.C. § 355(j)(2)(B), Sandoz certified to the FDA its belief that the '314 patent, the '460 patent, the '618 patent, and the '959 patent were invalid, unenforceable and/or would not be infringed by the manufacture, use or sale of Sandoz's Rosuvastatin Calcium Tablets, and Sandoz notified the Plaintiffs/counterclaim defendants of its belief that that the '314 patent, the '460 patent, and the '618 patent were invalid, unenforceable and/or would not be infringed by the manufacture, use or sale of Sandoz's Rosuvastatin Calcium Tablets.

64. Upon information and belief, one or more counterclaim defendants own and/or have the right to enforce the '314 patent, the '460 patent, the '618 patent and the '959 patent.

First Counterclaim– Declaratory Judgment That The '314 Patent Is Invalid

65. The counterclaim defendants filed a Complaint against Sandoz in this district alleging that Sandoz has infringed the '314 patent.

66. Sandoz incorporates by reference paragraphs 29-64 of this Answer as if fully set forth herein.

67. The '314 patent is invalid because it does not comply with one or more of the requirements of 35 U.S.C. §§ 101 *et seq.*

Second Counterclaim– Declaratory Judgment That The '314 Patent Is Unenforceable

68. Sandoz incorporates by reference paragraphs 29-67 of this Answer as if fully set forth herein.

69. The '314 patent is unenforceable for inequitable conduct as alleged.

Third Counterclaim – Declaratory Judgment That Sandoz's Rosuvastatin Calcium Tablets Do Not Infringe Any Valid Claim Of The '314 Patent

70. Sandoz incorporates by reference paragraphs 29-69 of this Answer as if fully set forth herein.

71. Sandoz's Rosuvastatin Calcium Tablets do not infringe any valid and enforceable claim of the '314 patent.

Fourth Counterclaim– Declaratory Judgment That The Claims Of The '460 Patent Are Invalid

72. Sandoz incorporates by reference paragraphs 29-71 of this Answer as if fully set forth herein.

73. One or more claims of the '460 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101 *et seq.*

Fifth Counterclaim– Declaratory Judgment That Sandoz's Rosuvastatin Calcium Tablets Do Not Infringe Any Valid Claim Of The '460 Patent

74. Sandoz incorporates by reference paragraphs 29-73 of this Answer as if fully set forth herein.

75. Sandoz's Rosuvastatin Calcium Tablets do not infringe any valid claim of the '460 patent.

Sixth Counterclaim– Declaratory Judgment That The Claims Of The '618 Patent Are Invalid

76. Sandoz incorporates by reference paragraphs 29-75 of this Answer as if fully set forth herein.

77. One or more claims of the '618 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101 *et seq.*

Seventh Counterclaim– Declaratory Judgment That Sandoz's Rosuvastatin Calcium Tablets Do Not Infringe Any Valid Claim Of The '618 Patent

78. Sandoz incorporates by reference paragraphs 29-77 of this Answer as if fully set forth herein.

79. Sandoz's Rosuvastatin Calcium Tablets do not infringe any valid claim of the '618 patent

Eighth Counterclaim– Declaratory Judgment That The Claims Of The ‘959 Patent Are Invalid

80. Sandoz incorporates by reference paragraphs 29-79 of this Answer as if fully set forth herein.

81. One or more claims of the ‘959 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101 *et seq.*

Ninth Counterclaim – Declaratory Judgment That Sandoz’s Rosuvastatin Calcium Tablets Do Not Infringe Any Claim Of The ‘959 Patent

82. Sandoz incorporates by reference paragraphs 29-81 of this Answer as if fully set forth herein.

83. Sandoz’s Rosuvastatin Calcium Tablets do not infringe any valid claim of the ‘959 patent.

SANDOZ’S PRAYER FOR RELIEF

WHEREFORE, Sandoz requests the following relief:

- A. Dismissal of Plaintiffs’ claims in their entirety with prejudice;
- B. That Sandoz be awarded its costs and disbursements in this action;
- C. That the Court issue an Order declaring all claims of the ‘314 patent invalid;
- D. That the Court issue an Order declaring all claims of the ‘314 patent unenforceable;
- E. That the Court issue an Order declaring that Sandoz’s Rosuvastatin Calcium Tablets do not infringe any valid and enforceable claim of the ‘314 patent;
- F. That the Court issue an Order declaring all claims of the ‘460 patent invalid;
- G. That the Court issue an Order declaring that Sandoz’s Rosuvastatin Calcium Tablets do not infringe any valid claim of the ‘460 patent;

- H. That the Court issue an Order declaring all claims of the '618 patent invalid;
- I. That the Court issue an Order declaring that Sandoz's Rosuvastatin Calcium Tablets do not infringe any valid claim of the '618 patent;
- J. That the Court issue an Order declaring all claims of the '959 patent invalid;
- K. That the Court issue an Order declaring that Sandoz's Rosuvastatin Calcium Tablets do not infringe any valid claim of the '959 patent;
- L. That the Court declare this case to be exceptional pursuant to 35 U.S.C. § 285, and award Sandoz its attorneys fees; and
- M. That Sandoz be awarded such other and further relief as this Court may deem just and proper.

Dated: January 31, 2008

Respectfully submitted,

By: _____
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CERTIFICATE OF SERVICE

I, George H. Seitz, III, Esquire, hereby certify that on January 31, 2008, a true and correct copy of the foregoing *Answer, Affirmative Defenses and Counterclaims of Defendant Sandoz, Inc.* was filed electronically via the CM/ECF. In addition, this document was served via first class mail on the following:

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